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UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

**HARRISON RESEARCH LABORATORIES,
INC.,**

Plaintiff,

V.

**HCRAMERICA, LLC and HARRISON
CLINICAL RESEARCH GROUP GMBH,**

Defendants.

:
:
:
: **Civil Action No. 09-cv-6326-DMC-JAD**

: DEFENDANTS' MEMORANDUM
: IN OPPOSITION TO PLAINTIFF'S
: MOTION TO STRIKE

x

**HCRAMERICA, LLC and HARRISON
CLINICAL RESEARCH GROUP GMBH,**

Counterclaimants,

V.

**HARRISON RESEARCH LABORATORIES,
INC.,**

Counterclaim-Defendant.

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INTRODUCTION

Defendants' Counterclaims against Plaintiff Harrison Research Laboratories, Inc. ("HRL") accurately state that HRL was criminally convicted of attempting to tamper with key documents in connection with a U.S. Environmental Protection Agency ("EPA") audit of HRL's work, and that HRL's President, Lynne Harrison, was convicted of testing pesticides on more than 300 people without first properly obtaining their informed consent. Those statements are neither "impertinent," "immaterial" nor "gratuitous," as HRL contends. Rather, they underscore the false and misleading nature of HRL's advertising claim that it has "passed numerous USA FDA audits," which is at the heart of Defendants' Counterclaims.¹

HRL makes its false claim about having passed "numerous" FDA audits on its website and in its brochure in order to mislead prospective customers into thinking that the United States Government has given its imprimatur to HRL and its services. Combined with the fact that HRL has passed very few – rather than "numerous" – FDA audits, HRL's felony conviction for obstructing an EPA investigation strips away any pretense that the United States Government has blessed HRL and puts the lie to the message that HRL seeks to convey by its false and misleading representation.

In addition, HRL's conviction bears directly, and significantly, on one of the central issues in this case: whether the clinical trial-related services that Defendants Harrison Clinical Research Group GmbH ("HCRG") and HCRAmerica, LLC ("HCRA") (collectively "Defendants") perform are sufficiently different from the testing services performed by HRL as to dispel a likelihood of confusion. Defendants submit that a felony conviction such as that imposed upon HRL would, as a

¹ In its Memorandum, HRL seeks to create the erroneous impression that Defendants somehow "slipped in" the statement concerning the criminal convictions only after Defendants were granted leave to amend their Answer. *See* HRL Memorandum at 1, 2. In point of fact, that statement was, from the start, contained in the proposed Amended Answer that Defendants submitted to this Court -- the same Amended Answer that HRL elected not to oppose, that this Court authorized to be filed and that Defendants did file.

practical matter, prevent the convicted entity from participating in the type of therapeutic clinical trials that are the mainstay of Defendants' business. Yet HRL has been able to continue to conduct the type and volume of non-therapeutic testing for sunscreens, cosmetics, shampoo and other consumer products that it was performing prior to its conviction – a telling indication of the difference between the services that the parties perform.

HRL does not – and cannot – deny that it committed these serious breaches of data integrity and informed consent requirements. Nonetheless, HRL has moved to strike Defendants' assertions, claiming they are “impertinent and immaterial” to a case that involves drug and medical device companies' decisions to hire contract research organizations (“CROs”) to participate in critical human clinical trials for new drug and medical device approvals.

In a case decided in 2009, this Court reaffirmed that “motions to strike are highly disfavored.” *Eisai Co., Ltd. v. Teva Pharmaceuticals USA, Inc.*, 629 F.Supp.2d 416, 424 (D.N.J. 2009). As the Court observed, only if the allegations sought to be stricken “*have no possible relation to the controversy*” should the Court strike them. *Id.* (*emphasis supplied*). Because HRL's past misconduct goes to the essence of the data and study integrity on which FDA approvals of new drugs and medical devices so heavily depend, the failure to disclose the past convictions to prospective customers is highly material both to the misleading nature of HRL's claim that it has passed “numerous” FDA audits and to Defendants' defense on the merits. Accordingly, Defendants respectfully submit that this Court should deny HRL's Motion.

FACTUAL BACKGROUND

Defendants HCRG and HCRA are contract research organizations, as the FDA regulations define that term: parties to which a study sponsor such as a pharmaceutical company delegates specific portions of the sponsor's responsibilities in the conduct of a human clinical trial. 21 C.F.R. § 312.52. The results of such human clinical trials are used as the foundation for FDA approvals of

new medicines and medical devices worth many millions of dollars. Such trials themselves often cost millions of dollars to conduct.

HCRG is a German company that designs, supervises, monitors, audits, statistically analyzes and conducts such human clinical trials for new prescription drugs and medical devices, and has done so for more than twenty years. Over that time, U.S.-based companies have submitted the results of trials in which HCRG has participated to the FDA. HCRA is HCRG's United States affiliate. A large percentage of the clinical trials in which HCRG and HCRA participate are studies involving multiple clinical centers where patients are administered the product being evaluated and may receive therapeutic benefits from the new product. These clinical centers are sometimes located in different countries while engaged in the same clinical trial. Some of them have been located in the United States. Neither HCRG nor HCRA has a clinical testing site of its own in the United States or has any current plans to acquire one, given the low cost competition for such work from India and the fact that HCRG already has such a clinic in Germany.

Plaintiff HRL, by contrast, and as shown by its website and other evidence in this case, is a single-location testing site specializing in the testing of sunscreens, cosmetics and consumer products for skin and eye irritation -- work that is usually non-therapeutic and that differs markedly from therapeutic clinical trials for new prescription drugs or medical devices. Despite HRL's lack of any FDA-reported recent clinical trial experience, HRL, in its marketing material, claims that it has passed "numerous" FDA audits, claims that it conducts Phase 3 clinical trials and claims to conduct "the full range of human testing." It conspicuously fails to mention its felony conviction for trying to backdate informed consent forms when the United States Government began to audit HRL's work in 1997.

Given the absence of any identified confusion in the nearly 15 years that the parties have co-existed in the United States market, and given the significant difference between the type of work

that HRL and Defendants perform, potential future confusion, however remote, among customers is the only conceivable basis for HRL's trademark infringement claims.² This makes impediments to HRL's ability to perform the kind of therapeutic clinical trial work that Defendants do important both to whether HRL has any claim and to Defendants' Counterclaims for misleading advertising. HRL's and its President's convictions are such impediments, making them highly material to this case.

ARGUMENT

HRL asserts in its Memorandum that "the allegations about an EPA proceeding and the guilty pleas are – on their face – immaterial and impertinent." HRL Memorandum at 1. HRL fails to cite this Court's repeated decisions holding that motions to strike are highly disfavored and must be denied unless the allegation has no conceivable pertinence to the subject matter. *See, e.g., Eisai Co., Ltd.*, 629 F. Supp.2d at 424. In making this Motion, HRL betrays its apparent ignorance of the federal regulations governing human clinical trials and of the serious commercial impacts that a felony conviction for obstructing a Government investigation – if disclosed – may have on a study sponsor seeking a company to participate in human clinical trials that are regulated by the FDA.

This Court should deny the instant Motion. Defendants' undisputed allegations concerning HRL's prior wrongdoing are directly relevant to a decision by a pharmaceutical or medical device company to hire a company to participate in a clinical trial involving human subjects, such as the Phase 1, 2 and 3 human clinical trials on which the FDA relies to approve or reject applications to market new prescription medicines. The combination of HRL's grossly exaggerated claim that it has passed "numerous" FDA audits and its failure to mention its prior conviction creates a very

² In its Memorandum, HRL erroneously states that it owns a United States Registration for the mark HARRISON CLINICAL RESEARCH, INC. HRL Memorandum at 2. It does not. Rather, HRL owns a Registration for the mark HARRISON RESEARCH LABORATORIES, INC.

misleading portrait of its qualifications to prospective study sponsors, and thus bears directly on Defendants' Counterclaims.

I. MOTIONS TO STRIKE ARE HIGHLY DISFAVORED.

As stated, HRL, in its Memorandum, does not cite a single decision of this Court – or of any other Court within this Circuit – concerning motions to strike. Yet only last year, this Court reaffirmed that “motions to strike are highly disfavored.” *Eisai Co., Ltd.*, 629 F. Supp.2d at 424. *See also Garlanger v. Verbeke*, 223 F.Supp.2d 596, 609 (D.N.J. 2002); *Tonka Corp. v. Rose Art Indus., Inc.*, 836 F.Supp. 200, 217 (D.N.J. 1993). Where, as here, a party seeks to strike specific allegations in a pleading, the moving party must show that “*the allegations have no possible relation to the controversy and may cause prejudice to one of the parties, or...the allegations confuse the issues.*” *Eisai Co. Ltd.*, 629 F. Supp.2d at 425 (emphasis supplied). This Court went on to note that “[w]hen faced with allegations that could possibly serve to achieve a better understanding of claims or perform any useful purpose in promoting the just disposition of the litigation, courts generally deny such motions to strike.” *Id.* Indeed, “only allegations that are so unrelated to plaintiffs' claims as to be unworthy of any consideration should be stricken.” *Id.*, quoting *Johnson v. Anhorn*, 334 F.Supp.2d 802, 809 (E.D.Pa. 2004).³

Far from being “unworthy of consideration,” document tampering and failing to obtain proper consents from human subjects are highly pertinent to a case such as this, which involves drug

³ HRL relies on dicta from *Morris v. Weingarten*, 777 F.Supp. 312, 319 (S.D.N.Y. 1991), in which the court dismissed the entire case because of failure to state a claim for securities or other fraud. HRL Memorandum at 4-5. In that instance, the court stated that reference to Michael Milken's income was irrelevant and should be stricken; no income allegations are made here. The court also struck the reference to the prior conviction, but the court had already decided to dismiss the entire case. Plaintiff also relies on *Schulz v. Braga*, 290 F.Supp.2d 637 (D.Md. 2003), in which “the court struck allegations about a prior incident involving the defendants . . . because it was not in keeping with the spirit of notice pleading.” HRL Memorandum at 5. In fact, the court struck the allegations because it had dismissed the underlying claim on other grounds. *Schulz*, 290 F.Supp. at 655. Consequently, the *Schulz* case provides no support for HRL's motion to strike.

companies seeking to conduct human clinical trials, because such violations can have very serious legal, financial and reputational impacts on the study sponsor, as explained below.

II. ATTEMPTED FALSIFICATION OF STUDY DOCUMENTS AND FAILURE TO OBTAIN THE PROPER INFORMED CONSENT OF RESEARCH SUBJECTS CAN HAVE SERIOUS IMPACTS ON STUDY SPONSORS, MAKING FAILURE TO DISCLOSE SUCH PRIOR MISCONDUCT HIGHLY MATERIAL IN THIS CASE.

HRL argues, in essence, that its prior felony conviction for trying to backdate patient consent forms is irrelevant to the decisions of study sponsors as to whom to hire to conduct FDA-supervised therapeutic clinical trials. *See* HRL Memorandum at 5.⁴ Contrary to HRL's argument, however, applicable laws make prior convictions and misconduct critically important to a study sponsor seeking to hire a clinical investigator to participate in a clinical trial for FDA approval of a drug or medical device. This information is important because such misconduct can result in:

- tort liability to third-parties for the study sponsor;
 - securities law claims against the study sponsor;
 - FDA enforcement action against the study sponsor;
 - reputational damage to the study sponsor;
 - FDA invalidation of a study or studies submitted to the FDA by or for the study sponsor;
- and
- FDA delay, withdrawal or denial of approval of a new pharmaceutical or medical device of the study sponsor.

For a drug or device manufacturer, any of these potential results can have a very significant adverse financial impact.

⁴ HRL also tries to argue that its conviction and that of its President are too remote in time to be pertinent and have little to do with FDA matters. HRL Memorandum at 3, 5. Significantly, however, these convictions occurred in 2000 – five years after the last FDA audit of HRL. Since HRL effectively claims in its brochure and website that a 1995 FDA audit is recent enough for consideration, why is a felony conviction in 2000 too old to consider?

HRL was convicted in part of trying to cause a study sponsor to falsify patient consent forms for over 300 test subjects to show that those subjects knew that HRL would test pesticide compounds on them. *See* Exhibit A to the Certification of Lisa Ann T. Ruggiero, submitted herewith (“Ruggiero Cert.”). Falsification of consent forms can lead to significant liability claims against drug company sponsors by injured subjects. Thus, for example, in connection with a test of antibiotics on Nigerian children, a tort claim was stated against Pfizer based on allegations that it had “failed to secure the informed consent of either the children or guardians and specifically failed to disclose or explain the experimental nature of the study.” *Abdullahi v. Pfizer, Inc.*, 562 F.3d 163, 169 (2d Cir. 2009). Similarly, in another case, falsification of donor consent forms led to multi-district tort litigation decided in this Court. *In re Human Tissue Products Liability Litigation*, 582 F. Supp.2d 644, 649 (D.N.J. 2008).

False statements about clinical trials can also lead to securities litigation against the companies making such statements. *See, e.g., SEC v. Reys*, 2010 WL 1734843, *3- 5 (W.D. Wash. 2010)(refusing to dismiss SEC claims when defendant claimed that such misstatements were “immaterial”); *In re Neo-Pharm Inc. Securities Litigation*, 2010 WL 1335824, *17- 18 (N.D. Ill. 2010)(material omissions about clinical trials actionable); *Bilhofer v. Flamel Technologies SA*, 663 F. Supp.2d 288 (S.D.N.Y. 2009); *SEC v. Selden*, 632 F. Supp.2d. 91 (D. Mass. 2009); *In re SFBC Securities and Derivative Litigation*, 495 F. Supp.2d 477, 480 (D.N.J. 2007)(alleged falsification of test results in FDA clinical trials). These and many more reported cases demonstrate that alleged misstatements about clinical trial results and subsequent FDA action can subject the study sponsor to securities law claims.

Since September 2007, federal law has required that all Phase 2 and Phase 3 clinical trials for drugs and medical devices for serious or life-threatening diseases or conditions be registered with the federal government; since September 2008, all Phase 2 and Phase 3 clinical trials, whether or not for

serious or life-threatening diseases or conditions, must also be registered. 42 U.S.C. §282(j)(2)(C) (2006). Considerable information must be submitted by the sponsor or principal investigator of the clinical trial. *Id.* §282(j)(1)(A)(ix) (“responsible party” definition); §282(j)(2)(specifying multiple categories of data). Those data must be certified as truthful: “the clinical trial information submitted by a responsible party under this subsection shall not be false or misleading in any particular.” *Id.* §282(j)(5)(D). Where a party submits false or misleading information, the Director of the National Institutes of Health must include in the public registry a notice that the responsible party submitted false or misleading information. *Id.* §282(j)(5)(E)(i)(bb)(iv).

Furthermore, the FDA is obliged to withdraw approval of a new drug where untrue statements of material fact were included in the supporting application: “The [FDA] *shall*, after due notice and opportunity for hearing to the applicant, withdraw approval of an application with respect to any drug under this section if the Secretary finds (1) . . . ; or (5) *that the application contains any untrue statement of a material fact.*” 21 U.S.C. § 355(e) (2006) (emphasis supplied).

The FDA has stated in its public Compliance Policy Guidelines, Section 120.100, *see* Exhibit B to Ruggiero Cert., that where the FDA suspects data tampering or fraudulent statements, it will take strong action with respect to past and present drug applications:

If the agency determines that the criteria for approval cannot be met because of unresolved questions regarding reliability of data, the agency will not approve the application.

When FDA finds, based on fraudulent data in an application, that the data in the application are unreliable, the agency intends ordinarily to exercise its authority, under applicable statutes and regulations, to refuse to approve the application (in the case of a pending application) or to proceed to withdraw approval (in the case of an approved application), regardless of whether the applicant attempts to replace the unreliable data with a new submission in the form of an amendment or supplement. Thus, if the applicant wishes to replace the false data with a new submission, the new submission should be in the form of a new application. The new application should identify the parts of the original application that were found to be false. The truthfulness and accuracy of the new application

should be certified by the president, chief executive officer, or other official most responsible for the applicant's operations.

FDA also may seek recalls of marketed products and may request new testing of critical products. For drugs, for example, retesting may be requested for products that are difficult to manufacture or that have narrow therapeutic ranges. FDA may pursue other actions, including seizure, injunction, civil penalties, and criminal prosecution, under the act or other applicable laws, as necessary and appropriate.

FDA Compliance Guide, Section 120.100,
<http://www.fda.gov/ICECI/ComplianceManuals/CompliancePolicyGuidanceManual/ucm073837.htm> (emphasis supplied).

In order to cure such deficiencies, the FDA ordinarily requires not only a new application -- with substantial delays and costs imposed on the study sponsor -- but major changes in the corporate structure of the offending party:

Applicants who engage in wrongful acts ordinarily will need to take the following corrective actions to establish the reliability of data submitted to FDA in support of pending applications and to support the integrity of products on the market:

1. Cooperate fully with FDA and other Federal investigations to determine the cause and scope of any wrongful acts and to assess the effects of the acts on the safety, effectiveness, or quality of products;

2. *Identify all individuals who were or may have been associated with or involved in the wrongful acts and ensure that they are removed from any substantive authority on matters under the jurisdiction of FDA;*

Id. (emphasis supplied).

Lynne Harrison and Debra Harrison still control all of HRL's operations, just as they did at the time of HRL's efforts to tamper with the informed consent forms. According to public sources, HRL has fewer than 30 employees, including both Harrisons. There is no consent decree resolving or addressing HRL's past data handling misconduct. Consequently, if study sponsors know of the prior convictions, they will be very reluctant to hire HRL to participate in human clinical trials submitted to FDA for pre-market approval, such as those for prescription drugs or medical devices. This reluctance would likely be heightened because any testimony offered by Lynne Harrison would

be subject to impeachment because of her own conviction and her conceded involvement in the corporate conviction for attempted falsification of patient consent forms; indeed, Fed. R. Evid. 609(a)(2)'s automatic admission provision would apply. Consequently, study sponsors would have difficulty using HRL to defend the study results in any testimonial proceeding.

Under the circumstances, HRL's prior conviction for interfering with an EPA audit by attempting to backdate consent forms is clearly material to a study sponsor's decision to hire, or not hire, HRL to participate in a clinical trial for a product that is subject to FDA pre-market approval -- which is precisely the work that HCRG has performed for its customers for the past 20 years and that Defendants continue to perform. Thus, the information about HRL's prior conviction is highly relevant not only to HRL's trademark infringement claim, but also to Defendants' position in their Counterclaims that HRL's statement that it has "passed numerous FDA audits" is not only untrue but, given HRL's admitted obstruction of an EPA audit, egregiously misleading. Consequently, HRL's Motion To Strike should be denied.

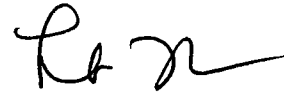
CONCLUSION

For the foregoing reasons, Defendants HCRG and HCRA respectfully submit that this Court should deny HRL's Motion To Strike, and grant Defendants such other relief as this Court may deem just and proper.

Dated: October 20, 2010

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